Montana Diabetes Surveillance & Clinical Communication

MONTANA DIABETES PROJECT

Montana Department of Public Health and Human Services
Chronic Disease Prevention and Health Promotion Program
Room C317, Cogswell Building
PO Box 202951
Helena, Montana 59620-2951

Issue: July - September 2003

TESTING FOR GLYCATED HEMOGLOBIN AND MICROALBUMINURIA IN MONTANA, 2002.

WHAT'S INSIDE

BACKGROUND

HbA1c [Hemoglobin A1c: a particular form of glycated hemoglobin]

Controlling blood glucose levels in patients with diabetes is important to prevent long-term complications from diabetes.[1,2] Over the past 10 years, glycemic control has been measured through testing for glycated hemoglobin, specifically hemoglobin A-one-C (HbA1c). The targets for glycemic control, HbA1c value <7.0%, are based on the findings from several clinical trials, including the Diabetes Control and Complications Trial (DCCT).[1-3]

In 1996, the National Glycohemoglobin Standardization Program (NGSP) was established to standardize glycated hemoglobin test results so that clinical laboratory results are comparable to those reported in the DCCT, where relationships to mean blood glucose values, HbA1c, and risk for vascular complications were first established.[4] Laboratories that use non-certified methods are not assured that their HbA1c values are traceable to the DCCT. A current listing of NGSP certified methods is available at www.missouri.edu/~diabetes/ngsp.html.

Microalbuminuria [a small amount of albumin in the urine]

A low level of albumin in the urine, termed microalbuminuria, is the earliest sign of diabetic nephropathy. Most authorities recommend routine screening for microalbuminuria to initiate and monitor clinical efforts to delay the progression of nephropathy.[5-7] The American Diabetes Association (ADA) and the American Association of Clinical Chemistry (AACC) have published clinical and laboratory recommendations for microalbuminuria screening.[5,8] The recommended tests for microalbuminuria screening, clinical cutoffs, and reporting units are displayed in Table 1. And, an algorithm for microalbuminuria screening recommended by the ADA is provided in Figure 1.

Figure 1. Screening for Microalbuminuria (reference 5).

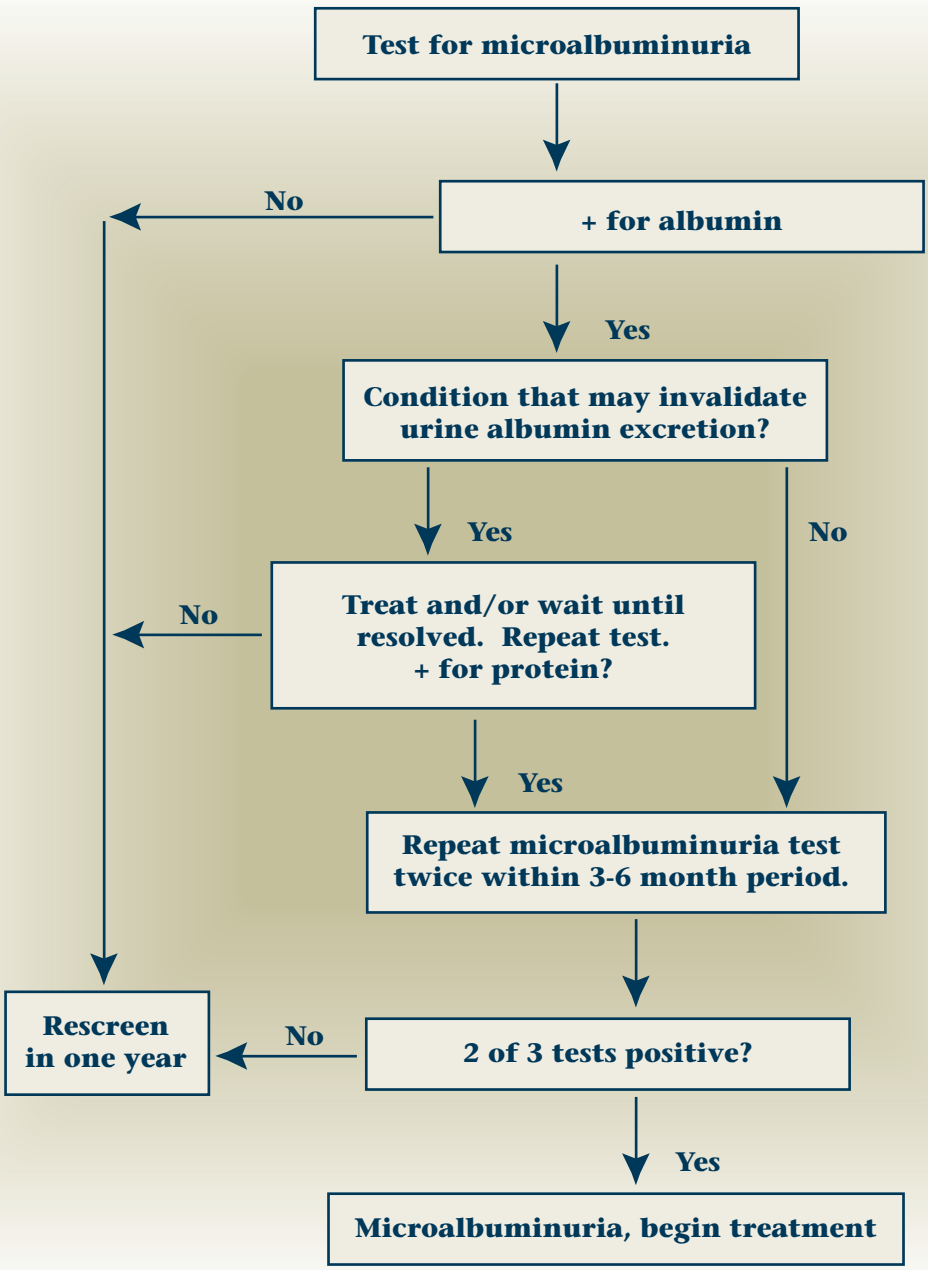


Table 1. Definitions of abnormalities in albumin excretion*.

	A/C RATIO+ (ug/mg creatinine)	24-HOUR COLLECTION (mg/24-h)	TIMED COLLECTION (ug/min)
Category			
Normal	<30	<30	<20
Microalbuminuria	30-299	30-299	20-199
Clinical albuminuria	≥300	≥300	≥200

*American Diabetes Association (reference 5)
+Albumin to creatinine ratio
Because of the variability in urinary albumin excretion, two to three specimens collected within a 3 to 6-month period should be abnormal before considering a patient to have crossed one of these diagnostic thresholds. Exercise within 24 hours, infection, fever, congestive heart failure, marked hyperglycemia, marked hypertension, pyuria, and hematuria may elevate urinary albumin excretion over baseline values.

To use both A1c and microalbuminuria testing to assess risk for complications and monitor therapies accurately requires communication between physicians and laboratories about which methods are being used and how the results are reported.[9] The Montana Diabetes Project surveyed laboratories in Montana in 1999 to ascertain what tests for microalbuminuria were available to clinicians and how the results were reported. Cutoffs and units reported from the survey did not always match the current recommendations.[10] A follow-up survey in 2002 also asked labs about HbA1c testing. This surveillance report summarizes the important findings from the 2002 survey, the results of which have been reported to all the laboratories and published.[11]

METHODS

One hundred and twenty-six laboratories in Montana (hospital-based, free standing, and physician office laboratories) and out-of-state reference laboratories that provide glycated hemoglobin and microalbuminuria testing to Montana facilities were surveyed by mail in January 2002. Laboratories were identified through the Montana Department of Public Health and Human Services office responsible for performing Clinical Laboratory Improvement Act surveys. Our survey assessed if laboratories provide testing for glycated hemoglobin and microalbuminuria, the methodology used for both tests, and the volume of glycated hemoglobin and microalbuminuria testing performed in the past month. In addition, labs were asked about the specific methods used for glycated hemoglobin testing, how results were reported and whether labs were aware of the NGSP. For microalbuminuria, labs were asked about the exact units used to report results of ratios and timed tests and values used to define cutoffs between normal and microalbuminuria.

RESULTS

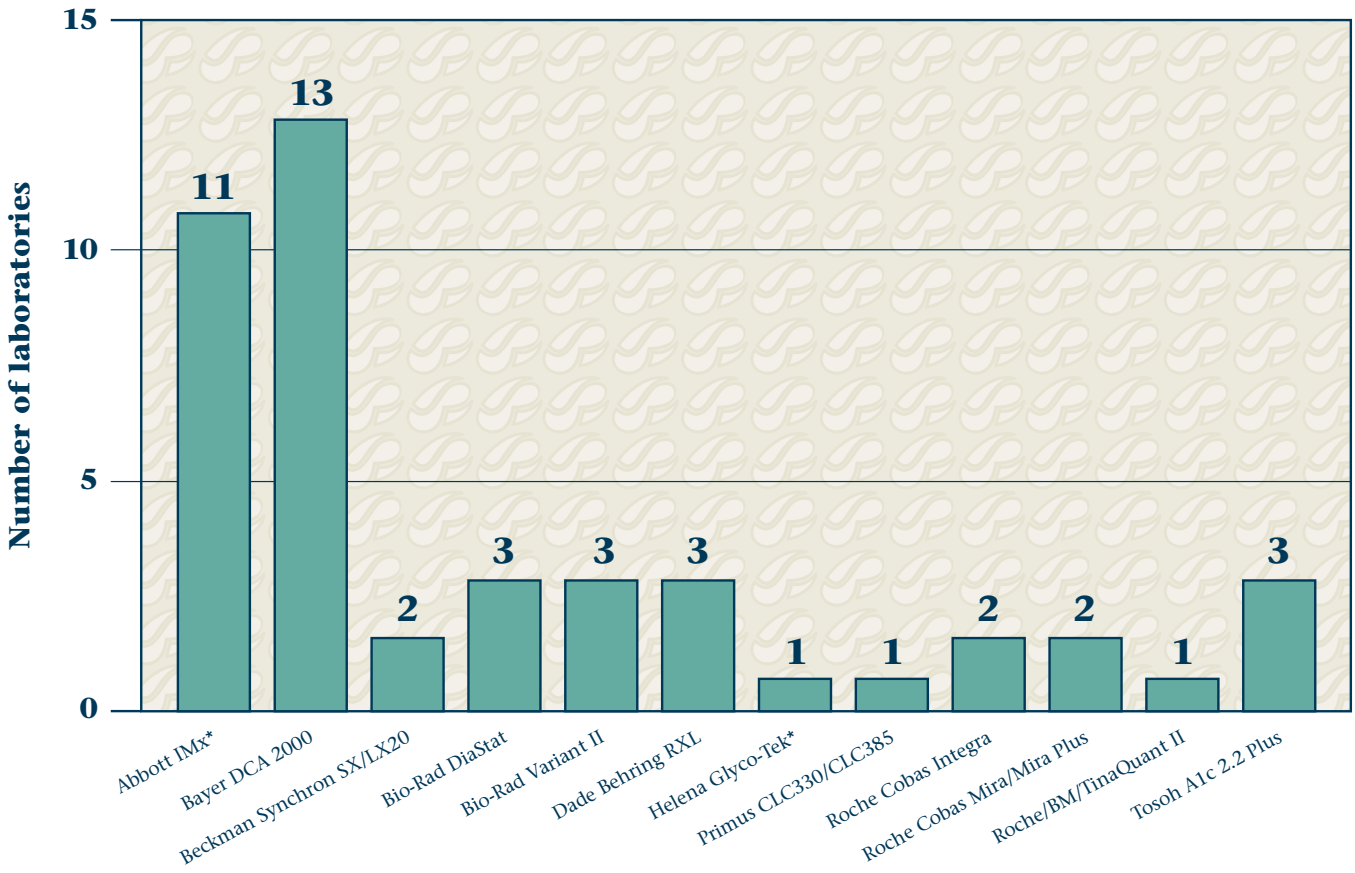
One hundred and three of the 126 laboratories responded to the survey (82%). Of the 103 responding laboratories, 40 (39%) were either hospital-based or reference laboratories and 65 (61%) were freestanding, physician office, or other laboratories.

Glycated hemoglobin testing

Forty-four percent of laboratories (n = 45) overall reported currently testing for glycated hemoglobin. Of the 56 laboratories not testing for glycated hemoglobin, 95% sent specimens to reference laboratories for this service. Of the 45 laboratories providing glycated hemoglobin testing, the majority (58%) performed ≤100 tests in the past month. Ninety-eight percent of laboratories testing for glycated hemoglobin, measured HbA1c, while fewer measured total glycated hemoglobin (29%), or total HbA1 (2%). Similarly, most laboratories reported results as % HbA1c values (98%), and few reported total glycated hemoglobin values (11%).

Less than half of responding laboratories that provided glycated hemoglobin testing were aware of the NGSP (42%), but 71% used NGSP-certified methods. The majority of laboratories testing for glycated hemoglobin used the Bayer DCA 2000 or the Abbott IMx (Figure 2). All of the methods used by laboratories testing for glycated hemoglobin, except the Abbott IMx and the Helena Glyco-Tek, were currently certified by the NGSP. One additional laboratory used a NGSP-certified method but reported only total glycated hemoglobin values. Laboratories aware of the NGSP were more likely to be using NGSP certified methods (54%) compared to laboratories not aware of the NGSP (8%).

Figure 2. Number of laboratories using each methodology for glycated hemoglobin testing. *Methods not certified by the National Glycated Hemoglobin Standardization Program.



Microalbuminuria testing practices

Overall 81 (79%) of the 103 responding laboratories provided quantitative microalbuminuria testing either on site or through a reference laboratory. Twenty-five (24%) of the 103 laboratories provided quantitative testing for microalbuminuria on site. The majority of these laboratories tested ≤100 specimens in the month (64%), 12% performed 101 to 500 tests per month, 16% performed more than 500 tests per month, and 8% did not specify the number of specimens tested. Of the 78 laboratories that did not test quantitatively on site, 56 (76%) sent specimens to a reference laboratory within or outside of Montana. Of the 25 in-state and out-of-state laboratories that performed testing for microalbuminuria, 23 laboratories offered A/C ratios (albumin to creatinine ratios), 17 offered 24-hour testing, and only 7 laboratories offered other timed tests (Table 2). However, only 14 of 23 laboratories performing A/C ratios reported results using recommended units and cutoff values. For 24-hour collections, 6 of 17 laboratories used the recommended units and cutoffs. For other timed collections, only 2 of 7 laboratories used the recommended units and cutoffs.

Table 2. Number of laboratories performing the 3 recommended tests for microalbuminuria on site and using the recommended ADA/NKF units and cutoff values for reporting.

TESTS	PERFORM TEST*	USED RECOMMENDED CUTOFF VALUES AND UNITS*
A/C ratio	23/25 (92)	14/23 (61)
24-hour	17/25 (68)	6/17 (35)
Timed collection	7/25 (28)	2/7 (29)

*Note. Values expressed are number/total number (percent).

DISCUSSION

Our survey of laboratories in Montana indicates that glycated hemoglobin testing is routinely provided in most community laboratories or through reference laboratories, and that most laboratories report results as % HbA1c. The use of NGSP-certified methods is comparable to that found in a recent assessment of laboratories through the College of American Pathologists survey, where 70% of laboratories used certified methods.[4] Less than half of responding laboratories testing for glycated hemoglobin were aware of the NGSP and over 25% used methods (Abbott IMx and Helena Glyco-Tek) that were not certified by NGSP. The current clinical laboratory recommendations suggest that glycated hemoglobin results be reported as % HbA1c and that NGSP certified methods be used to assure traceability to the Diabetes Control and Complications Trial. Our findings regarding urine microalbuminuria screening, in contrast to glycated hemoglobin testing, suggest that fewer laboratories provide this test onsite (<25%). In addition, when testing is available, results reported to primary care physicians may be difficult to interpret using the guidelines from the National Kidney Foundation and the ADA.[11] The availability of microalbuminuria testing remains limited, and reporting practices have not changed markedly since the 1999 survey.[10]

Clinicians may want to inquire about the microalbuminuria and glycated hemoglobin assays used in their laboratories to ensure that they are reported consistently with the current clinical recommendations and that certified methods are being utilized.

ACKNOWLEDGEMENTS

We thank each of the laboratories for completing the survey. We also thank Susan Day from the Montana Diabetes Project, Linda Priest and Abbie Pence from Northwest Resource Consultants, and Claudia Towne for their work and assistance on this project.

Reported by: [1]D Gohdes, [1]TS Harwell, [1]SD Helgerson, [2]RR Little, [1]JM McDowall, [3]RG Nelson, [1]CS Oser: [1]Montana DPHHS, Helena, Montana, [2]University of Missouri, School of Medicine, Columbia, Missouri, [3]National Institute of Diabetes, Digestive, and Kidney Diseases, Phoenix, Arizona.

REFERENCES

1. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med 1993;329:977-86.

2. UK Prospective Diabetes Study Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). Lancet 1998;352:837-52.

3. American Diabetes Association. Clinical practice recommendations. Diabetes Care 2002;25:S97-S99.

4. Little RR, Rohlfing CL, Wiedmeyer HM, Myers GL, Sacks DB, Goldstein DE, NGSP Steering Committee. The national glycohemoglobin standardization program: a five-year progress report. Clin Chem 2001;47(11):1985-92.

5. American Diabetes Association. Diabetic nephropathy. Diabetes Care 2003;23 (Suppl. 1):S94-S98.

6. Bennett PH, Haffner S, Kasiske BL, Keane WF, Mogensen CE, Parving HH, Steffes MW, Striker GE. Screening and management of microalbuminuria in patients with diabetes mellitus: recommendations to the Scientific Advisory Board of the National Kidney Foundation from an ad hoc committee of the Council on Diabetes Mellitus of the National Kidney Foundation. Am J Kidney Dis 1995;25(1):107-12.

7. World Health Organization. Prevention of diabetes mellitus: Report of the WHO study group. World Health Organization technical report series 844, Geneva, Switzerland, 1994.

8. Sacks DS, Bruns DE, Goldstein DE, Macclaren NK, McDonald JM, Parrott M. Guidelines and recommendations for laboratory analysis and in the diagnosis and management of diabetes mellitus. Clin Chem 2002;48:436-72.

9. Hostetter TH. Detecting early chronic kidney disease: are clinical laboratories a problem? Editorial. Am J Kid Dis 2003;42: 392-4.

10. Harwell TS, McDowall JM, Eyler N, Little RR, Helgerson SD, Gohdes D. Laboratory testing for microalbuminuria in the general community. Diabetes Care 2000;23:1028-30.

11. Harwell TS, Nelson RG, Little RR, McDowall JM, Helgerson SD, Gohdes D. Testing for microalbuminuria in 2002: barriers to implementing current guidelines. Am J Kid Dis 2003; 42: 245-8.

NATIONAL DIABETES EDUCATION INITIATIVE

The National Diabetes Education Initiative (NDEI) provides ongoing education programs on type 2 diabetes and insulin resistance for health care professionals. These CME opportunities include:

- Clinical Insights in Diabetes - Monthly summaries of recent studies along with other useful information provided by fax or e-mail
- Online CME programs
- Interactive case studies
- Dinner conferences
- Audio conferences
- Power Point slides with lectures

To take advantage of these educational opportunities, just go to WWW.NDEI.ORG and enroll.

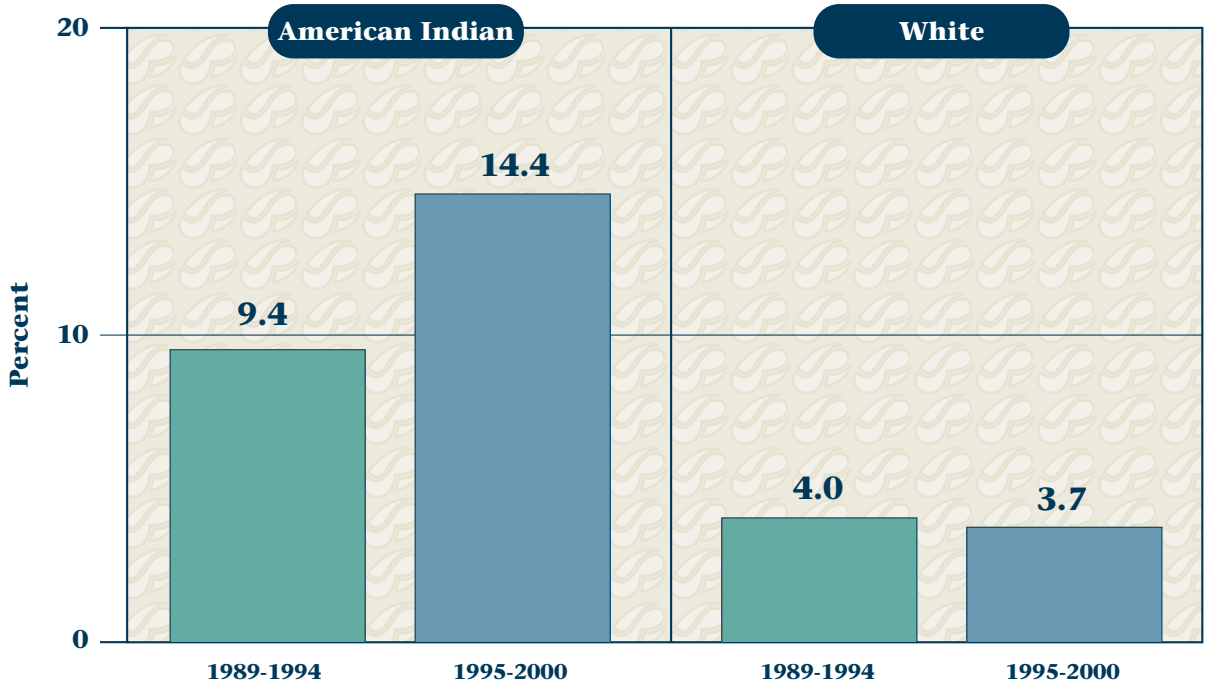
ERRATTA

In the April – June 2003 issue of the surveillance report there were two typographical errors. The corrections are listed below.

- Parity of American Indian mothers with diabetes in pregnancy was significantly greater compared to white mothers with diabetes (mean 2.0 vs. 1.3). Parity was also significantly higher in American Indian mothers without diabetes compared to white mothers without diabetes (mean 1.4 vs. 1.0).

- The legend for figure 5 was incorrectly labeled. The corrected legend and figure are displayed below.

Figure 5. Among American Indian and White women with diabetes during pregnancy, the percent with high birth weight (≥4500 grams) babies, Montana, 1989-2000.



WHAT IS THE MONTANA DIABETES PROJECT AND HOW CAN WE BE CONTACTED:

The Montana Diabetes Project is funded through a cooperative agreement with the Centers for Disease Control and Prevention, Division of Diabetes Translation (U32/CCU815663-05). The mission of the Diabetes Project is to reduce the burden of diabetes and its complications among Montanans. Our web page can be accessed at http://ahec.msu.montana.edu/diabetes/default.htm.

For further information please contact us at:

Project Coordinator:
Todd Harwell, MPH
Phone 406/444-1437
Fax 406/444-7465
e-mail tharwell@state.mt.us

Education Coordinator:
Marcene Butcher, RD, CDE
Phone 406/444-6677
e-mail marcibutcher@msn.com

Cardiovascular and Diabetes Epidemiologist
Carrie Oser, MPH
406-444-4002
e-mail coser@state.mt.us

Quality Improvement Coordinator:
Janet McDowall, RN
Phone 406/248-1270
e-mail jmcdowall@state.mt.us

Project Assistant:
Susan Day
Phone 406/444-6677
e-mail sday@state.mt.us

Quality Improvement Coordinator:
Elizabeth "Liz" Johnson, RN, CNP
Phone 406/444-0593
e-mail lizj@state.mt.us

MONTANA DIABETES SURVEILLANCE & CLINICAL COMMUNICATION

MONTANA DIABETES PROJECT

Montana Department of Public Health and Human Services
Chronic Disease Prevention and Health Promotion Program
Room C317, Cogswell Building
PO Box 202951
Helena, Montana 59620-2951